4-13-04



## Attorney Docket No. VPI/99-100DIV2

Applicants

Michael R. Hale, et al.

Application No.

10/613,650

Confirmation No.: 4616

**Filed** 

: July 2, 2003

For

INHIBITORS OF ASPARTYL PROTEASE

**Group Art Unit** 

1614

**Examiner** 

Not yet assigned

New York, New York 10020

**April 12, 2004** 

Hon. Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

"Express Mail" mailing label number EV132198523US

Date of Deposit April 12, 2004

I hereby certify that this paper/fee is being deposited with the United States Postal Service "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Hon. Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313.

Claire J. Saintil-van Goodman

#### Encl:

- Transmittal Letter (in duplicate);
- Information Disclosure Statement (in duplicate);
- Form PTO-1449 (in duplicate)

## <u>VPI/99-100DIV2</u>



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Not Yet Assigned

Group : 1614

Applicants : Michael R. Hale, et al.

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New York, New York April 12, 2004

Hon. Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

TRANSMITTAL LETTER FOR

## INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith is an Information Disclosure

Statement in the above-identified application. This

Statement is submitted:

- [ ] within three months of the application filing date;
- [x] more than three months from the application filing date but before the mailing date of the first Office Action on the merits.

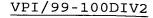
In accordance with 37 C.F.R. §§ 1.97(b)(3), submission of this Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge payment of any fees required in

connection with this Information Disclosure Statement to Deposit Account No. 06-1075. A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,

James F. Haley, Jr. (Reg. No. 27,794) Min Wang (Reg. No. 51,303) Attorneys for Applicants

c/o FISH & NEAVE
 Customer No. 1473
 1251 Avenue of the Americas
 New York, New York 10020-1104
 Tel.: (212) 596-9000





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Alexandria, Virginia 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and 1.97, applicants, through their representatives, make of record the following documents:\*

## UNITED STATES PATENTS

Inventor	Patent No.	Issue Date
Ryono et al.	4,629,724	December 16, 1986
Tung et al.	5,723,490	March 3, 1998
Vasquez et al.	5,843,946	December 1, 1998

For the convenience of the Examiner, a completed Form PTO-1449 listing these documents, is attached. Copies of all the documents listed herein were submitted by applicants in the grandparent United States Patent Application No. 09/500,781, now United States Patent 6,319,946; or were cited by the Examiner during prosecution of the parent United States Patent Application No. 09/927,271, now United States Patent 6,617,350. Pursuant to 37 C.F.R. §1.98(d), applicants have not enclosed copies of the listed documents. However, applicants stand ready to provide copies at the Examiner's request.

#### FOREIGN PATENTS

Country	Patent No.	Publication Date
EPO	EP 0159156A1	October 23, 1985
EPO	EP 0594540A1	April 27, 1994
PCT	WO 94/04492	March 3, 1994
PCT	WO 94/05639	March 17, 1994
PCT .	WO 94/10136	May 11, 1994
PCT	WO 95/06030	March 2, 1995
PCT	WO 95/07269	March 16, 1995
PCT	WO 95/09843	April 13, 1995
PCT	WO 95/14016	May 26, 1995
PCT	WO 95/32185	November 30, 1995
PCT	WO 96/33187	October 24, 1996

## OTHER DOCUMENTS

- A.K. Ghosh et al., "Potent HIV Protease Inhibitors Incorporating High-Affinity  $P_2$ -Ligands and (R)- (Hydroxyethylamino)sulfonamide Isostere," Bioorg. Med. Chem. Lett., 8, pp. 687-690 (1998).
- S. J. Hays et al., "Synthesis of cis-4-(Phosphonooxy)-2-piperidinecarboxylic Acid, an N-Methyl-D-aspartate Antagonist," J. Org. Chem., 56, pp. 4084-4086 (1991).
- Y. Kiso et al., "'O→N Intramolecular Acyl Migration'-type Prodrugs of Tripeptide Inhibitors of HIV Protease,"

  Peptides: Chemistry, Structure and Biology, 61, pp. 157-159 (1996).
- A.C. Nair et al., "A Computational Study of the Resistance of HIV-1 Aspartic Protease to the Inhibitors ABT-538 and VX-478 and Design of New Analogues," <u>Biochem. Biophys. Res. Commun.</u>, 242, pp. 545-551 (1998).
- J.W. Perich et al., "The Synthesis of Multiple O-Phosphoseryl-Containing Peptides via Phenyl Phosphate Protection," J. Org. Chem., 53, pp. 4103-4105 (1988).
- M.S. Plummer et al., "Design of Peptidomimetic Ligands for the pp $60^{\rm src}$  SH2 Domain," <u>Bioorganic & Medicinal Chemistry</u>, 5, pp. 41-47 (1997).

S. Yamaguchi et al., "Synthesis of HIV Protease Dipeptide Inhibitors and Prodrugs," <u>Peptide Chemistry 1996</u>, pp. 297-300 (1997).

Banker et al., Modern Pharmaceutics, pp. 627-629 (1996).

C.T. Baker et al., "Design, Synthesis and Conformational Analysis of A Novel Series of HIV Protease Inhibitors," Bioorg. & Med. Chem. Lett., vol. 8, pp. 3631-3636 (1998).

Applicants respectfully request that the above-cited documents be (1) fully considered by the Examiner during the course of the examination of this application and (2) printed on any patent issuing from this application. Applicants also request that a copy of the enclosed Form PTO-1449 duly initialed by the Examiner be forwarded to the undersigned with the next communication.

Respectfully submitted,

James F. Haley, Jr. (Reg. No. 27,794) Min Wang (Reg. No. 51,303)

Attorneys for Applicants

c/o FISH & NEAVE
 Customer No. 1473
 1251 Avenue of the Americas
 50th Floor
 New York, New York 10020-1104

Tel: (212) 596-9000

ATTY. DOCKET NO. U.S. DEPARTMENT OF COMMERCE **APPLICATION FORM PTO-1449** PATENT AND TRADEMARK OFFICE VPI/99-100DIV2 NO.: 10/613,650 **APPLICANTS CONFIRMATION NO.:** INFORMATION DISCLOSURE Michael R. Hale, et al. 4616 STATEMENT BY APPLICANT FILING DATE **GROUP** July 2, 2003 1614 U.S. PATENT DOCUMENTS FILING DATE EXAMINER **DOCUMENT CLASS SUBCLASS** DATE NAME IF INITIAL NUMBER **APPROPRIATE** 4,629,724 12/16/86 Ryono et al. Vasquez et al. 5,843,946 12/1/98 3/3/98 Tung 5,723,490 FOREIGN PATENT DOCUMENTS **TRANSLATION EXAMINER DOCUMENT COUNTRY CLASS SUBCLASS** DATE NUMBER INITIAL YES NO EP 0 159 156 10/23/85 0 594 540 A1 4/27/94 EP WO94/04492 3/3/94 **PCT** PCT WO94/05639 3/17/94 **PCT** WO94/10136 5/11/94 PCT WO95/06030 3/2/95 WO95/07269 3/16/95 PCT WO95/09843 PCT 4/13/95 WO95/14016 5/26/95 PCT WO95/32185 11/30/95 PCT WO96/33187 PCT 10/24/96

**EXAMINER** 

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

**FORM PTO-1449** 

# U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

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ATTY. DOCKET NO.	APPLICATION	
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Michael R. Hale, et al.	4616	
FILING DATE	GROUP	
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

et al., "Potent HIV Protease Inhibitors Incorporating High-Affinity P₂-Ligands and (R)- lamino)sulfonamide Isostere," Bioorg. Med. Chem. Lett., 8, pp. 687-690 (1998).  al., "Synthesis of cis-4-(Phosphonooxy)-2-piperidinecarboxylic Acid, an N-Methyl-D- tagonist," J. Org. Chem., 56, pp. 4084-4086 (1991).  , ""O→N Intramolecular Acyl Migration'-type Prodrugs of Tripeptide Inhibitors of HIV eptides: Chemistry, Structure and Biology, 61, pp. 157-159 (1996).  al., "A Computational Study of the Resistance of HIV-1 Aspartic Protease to the Inhibitors I VX-478 and Design of New Analogues," Biochem. Biophys. Res. Commun., 242, pp. 545- et al., "The Synthesis of Multiple O-Phosphoseryl-Containing Peptides via Phenyl rotection," J. Org. Chem., 53, pp. 4103-4105 (1988).
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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.					
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			APPLICANTS CONFIRMATION NO.: Michael R. Hale, et al. 4616				
			FILING DATE July 2, 2003		GROUP 1614		
		U.S.	PATENT DOCUME	ENTS			, <del>-</del>
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING II APPRO	F
	4,629,724	12/16/86	Ryono et al.				· · · · · · · · · · · · · · · · · · ·
	5,843,946	12/1/98	Vasquez et al.			<u> </u>	<del>·</del>
	5,723,490	3/3/98	Tung				<del> </del>
		FOREIC	ON PATENT DOCU	JMENTS			
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANS YES	LATION NO
	0 159 156	10/23/85	EP				
	0 594 540 A1	4/27/94	EP				
	WO94/04492	3/3/94	PCT				
	WO94/05639	3/17/94	PCT				
	WO94/10136	5/11/94	PCT				
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ATTY. DOCKET NO. VPI/99-100DIV2 APPLICANTS APPLICATION NO.: 10/613,650

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